IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

OUTSOURCING FACILITIES ASSOCIATION, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Civil Action No. 4:24-cv-00953-P

[Proposed] Order Granting Motion For Preliminary Injunction and Stay Pending Review

This case comes before the Court on the motion of Plaintiffs Outsourcing Facilities Association ("OFA") and North American Custom Laboratories, LLC, doing business as FarmaKeio Custom Compounding ("FarmaKeio"), for a preliminary injunction and stay pending review prohibiting the Food and Drug Administration ("FDA") from taking action against OFA members and FarmaKeio based on their compounding of the drug ingredient Tirzepatide pending final judgment in this case.

Finding good cause for the motion, the Court **GRANTS** the motion on the terms stated below. The Court states the good cause supporting this order as follows:

A plaintiff seeking a preliminary injunction "must establish (1) a likelihood of success on the merits; (2) a substantial threat of irreparable injury; (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted; and (4) that the grant of an injunction will not disserve the public interest." *Ladd v. Livingston*, 777 F.3d 286, 288 (5th Cir. 2015) (quoting *Trottie v. Livingston*, 766 F.3d 450, 452 (5th Cir. 2014)). The standards for securing a stay under 5 U.S.C. § 705 are substantially the same. *Airlines for America v. Dep't of Trans.*, 110 F.4th 672, 674 (5th Cir. 2024). Plaintiffs have established these elements.

1. Plaintiffs have a substantial likelihood of success on the merits. FDA removed Tirzepatide from the shortage list (the "Delisting Action") without notice-and-comment rulemaking required by the Administrative Procedure Act ("APA"). *See* 5 U.S.C. § 553(c). The Delisting Action is an agency "rule," because it qualifies as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4). And the Delisting Action is a substantive rule because it has "the force and effect of law." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 103 (2015). When FDA removes a drug from the shortage list, permissions under the Food, Drug, and Cosmetic Act ("FCDA") for compounding from bulk substances of the drug (Section 503B) or compounding copies of the drug (Section 503A) are eliminated, which renders formerly lawful activity unlawful. For that reason, the Delisting Action is not exempt from notice-and-comment process as informal adjudication. *See City of Arlington, Tex. v. F.C.C.*, 668 F.3d 229, 242 (5th Cir. 2012) (issuance of a generally applicable legal prohibition "is classic rulemaking"). Nor does anything in the FDCA exempt FDA from notice-and-comment rulemaking when it undertakes relevant actions.

Separately, Plaintiffs are likely to prevail because of FDA's lack of reasoned decisionmaking. Whether or not notice-and-comment rulemaking is mandated, an agency must justify its final action with a "reasoned analysis." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). Here, FDA failed to provide "a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Id.* at 43 (citation omitted). The agency itself framed it, FDA's analysis required determinations of supply and demand within a particular time period, but the Delisting Action identifies no applicable time period, makes an unfounded finding of monthly supply and offers no finding of demand by month (or any other time period), and it ignores substantial evidence in the data it relied on that monthly demand exceeds monthly supply. Further, FDA "treated conflicting evidence here with an almost breathtaking lack of evenhandedness." *Sutter E. Bay Hosps. v. N.L.R.B.*, 687 F.3d 424, 437 (D.C. Cir. 2012).

2. All equitable factors also favor an injunction. Absent immediate relief, FarmaKeio and OFA members will be irreparably harmed. *See, e.g.*, *Wages & White Lion Invs., LLC v. United States Food & Drug Admin.*, 16 F.4th 1130, 1142 (5th Cir. 2021) (holding that plaintiff proved irreparable harm based on FDA's action forbidding its product manufacturing and marketing). They will suffer financial loses that "cannot be undone through monetary remedies," *Interox Am. v. PPG Indus., Inc.*, 736 F.2d 194, 202 (5th Cir. 1984), given that sovereign immunity forecloses any monetary recovery in this case, *Wages & White Lion*, 16 F.4th at 1142.

The balance of harms and public interest also favor an injunction. These factors "'merge when the Government is the opposing party,'" *Texas v. Becerra*, 577 F. Supp. 3d 527, 561 (N.D. Tex. 2021) (quoting *Nken v. Holder*, 556 U.S. 418, 435 (2009)), and they favor an injunction. The public has a substantial interest in continued access to compounded Tirzepatide at least until the Court decides the pending preliminary-injunction motion. The public also has a "substantial public interest in having governmental agencies abide by the federal laws that govern their existence and operations." *Texas v. United States*, 40 F.4th 205, 229 (5th Cir. 2022).

A preliminary injunction will impose no cognizable harms. FDA will not suffer harm from following congressional dictates and making a reasonably informed—rather than arbitrary—decision. Nor is there harm in a temporary continuation of compounding that was lawful in FDA's own view for much of last year and had been continuously meeting public demand and patient needs since December 2022. FDA's basis for declaring the shortage over was unrelated to public health or safety, and maintaining an effective state of shortage does nothing to prevent FDA from enforcing the many mechanisms of the FDCA designed to protect public safety. *See, e.g.*, 21 U.S.C. § 353b(b)(1) and (2) (registration, inspection, and reporting requirements); *id.* § 353b(a)(4) (FDA prerogative to forbid outsourcing-facility compounding where "drugs or components of such drugs have been found to be unsafe or not effective"); *id.* § 353a(b)(1) (quality standards); *id.* § 353a(b)(3) (FDA prerogative to forbid pharmacy compounding of drug "that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product").

3. No security is necessary to support a preliminary injunction under Federal Rule of Civil Procedure 65(c). The amount of security required "is a matter for the discretion of the trial court," and the Fifth Circuit has held district courts have discretion to "require no security at all." *Kaepa, Inc. v. Achilles Corp.*, 76 F.3d 624, 628 (5th Cir. 1996) (citing *Corrigan Dispatch Company v. Casa Guzman*, 569 F.2d 300, 303 (5th Cir. 1978)). FDA will not suffer financial harm from an injunction that would make a security requirement proper, so the Court exercises its discretion to require no security.

For the foregoing reasons, the Court **GRANTS** Plaintiffs' motion for a preliminary injunction and stay pending review and **ENJOINS** for the pendency of this action or until further order of this Court the Food and Drug Administration from taking action against Plaintiffs or their members for engaging in compounding or distribution of Tirzepatide that is lawful in circumstances where Tirzepatide is named on the drug-shortage list so long as that compounding complies with conditions applicable in circumstances where Tirzepatide is named on the drug-shortage list.

IT IS SO ORDERED.

Dated: _____

_____
United States District Judge